COVID-19 challenge — Point of Care and Home Diagnostic Kit for COVID-19

Sponsor

Public Health Agency of Canada (PHAC)

Program

COVID-19 Challenge — Point of Care and Home Diagnostic Kit for COVID-19

For More Information

For additional information, please visit the <u>COVID-19 Challenge website</u> [1].

Description

Please note - The primary applicant for this program must be a for-profit small business meeting Innovative Solutions Canada's <u>eligibility criteria</u> [2]. Award recipients may subcontract a portion of the R&D work to an academic partner. Applicants/Bidders must perform at least two-thirds (2/3) of the research and development (R&D) work in Phase 1 and a half (1/2) of the work for Phase 2. The remaining R&D can be sub-contracted to other organizations or individuals.

Innovative Solutions Canada has dedicated funding to help combat current and future outbreaks of the novel coronavirus (COVID-19) and other similar threats. This program will help support the Government of Canada's fight against COVID-19 by funding R&D and testing prototypes in real-life settings that can help protect Canadians.

The emergency of SARS-CoV-2 has, in short order, reshaped Canadian society. In a matter of weeks, Canadians from coast to coast have had to engage in social distancing, while at the same time health care systems are threatened by a potential influx of severe cases, while the economy is distressed by a forced prorogation of economic activity. The response to this pandemic hinges on an all-of-society response, with frequent and timely lab testing as a central pillar of this work.

While molecular based detection of the virus remain as the mainstay of testing, this approached is hampered by intermittent shortages of swabs, viral transport media and molecular reagents. The Public Health Agency of Canada is thus in need of a novel approach to diagnostic testing that can rapidly and accurately detect the virus or a component of the virus that causes

COVID-19 without the need for traditional reagents and highly specialized equipment. Such a device can facilitate diagnosis and care (particularly in remote areas), while expanding into non-traditional clinical environments or home settings, enabling the broadest potential response to this monumental crisis.

The proposed solution must:

Phase 1 requirements:

- Detect SARS-CoV-2 (the causative agent of COVID-19) within the first 72 hours of symptoms with an accuracy similar to molecular RNA detection.
- Results should be available 20 minutes (at most) from sample collection to diagnosis.
- The sample input must be one other than a nasopharyngeal swab.
- The device must be single use.
- The device price cannot exceed \$40.
- The device must be usable by a lay person with no technical training (although an instruction sheet is allowable).
- The interpretation of the result should be easy for a lay person (i.e. negative or positive).
- Each device should possess a unique identifier (i.e serial code, QR or bar code).

Phase 2 requirements:

- Demonstrate, at the end of Phase 2, clinical efficacy data derived from a clinical trial comparing the device to the performance of the current gold standard.
- The gold standard is molecular detection by nasopharyngeal swab collection using two gene targets (the E and RdRp genes).
- Gold standard testing can be performed by the National Microbiology Laboratory or an accredited lab provided the samples are submitted in a blinded and anonimised fashion.
- Trial design should follow a non-inferiority trial design.

Eligibility

Solution proposals can only be submitted by a small business that meets all of the following criteria:

- for profit
- incorporated in Canada (federally or provincially)
- 499 or fewer full-time equivalent (FTE) employees
- research and development activities that take place in Canada
- 50% or more of its annual wages, salaries and fees are currently paid to employees and contractors who spend the majority of their time working in Canada
- 50% or more of its FTE employees have Canada as their ordinary place of work
- 50% or more of its senior executives (Vice President and above) have Canada as their principal residence

Applicants/bidders are allowed to use sub-contractors to perform the anticipated work in Phases

1 and 2. Sub-contractor(s) may be academic, industrial or not-for-profit. Applicants/Bidders must perform at least two-thirds (2/3) of the research and development (R&D) work in Phase 1 and a half (1/2) of the work for Phase 2. The remaining R&D can be sub-contracted to other organizations or individuals.

Funding Availability

- The maximum funding available for any Phase 1 Grant resulting from this Challenge is \$300,000.00 CAD for up to 3 months.
 - Estimated number of Phase 1 grants: 2
- The maximum funding available for any Phase 2 Grant resulting from this Challenge is \$2,000,000.00 CAD for up to 12 months. Only eligible businesses that have completed Phase 1 could be considered for Phase 2.
 - Estimated number of Phase 2 grants: 1

Maximum Project Value

Please see 'Funding Availability' for details.

Indirect Costs

15%

Project Duration

- Phase 1 projects have a maximum duration of 3 months.
- Phase 2 projects have a maximum duration of 12 months

Special Notes

Phase 1: Proof of Feasibility

The objective of Phase 1 is for selected applicants to conduct R&D on their proposed solutions and deliver a proof of feasibility to Canada.

Applicants are encouraged to progress their solution as far as possible on the Technology Readiness (TRL) scale, but note that Canada will only fund R&D through an ISC grant up to the end of TRL 6 under Phase 1.

Applicants that demonstrate successful completion of Phase 1 will be invited to submit a proposal for Phase 2.

Phase 2: Prototype Development

The objective of Phase 2 is to continue the R&D efforts of the proposed solution with the goal of developing a prototype ready for commercialization up to the end of TRL 9. Applicants are encouraged to progress their solution as far as possible on the TRL scale during this phase.

Entry into Phase 2 is solely limited to small businesses who have demonstrated successful completion of Phase 1 and who still meet the eligibility criteria. Small businesses that demonstrate successful completion of Phase 1 will receive an invitation from Canada to submit a proposal. The Phase 2 proposal will be evaluated against criteria that are the same or similar to those in Attachment 1 of this document. Participation in Phase 2 is not guaranteed. It is at the sole discretion of Canada to proceed with Phase 2.

Once Phase 2 is completed, no follow-on funding will be available for the solution from the ISC program.

Please refer to the <u>Office of Research COVID 19 web-page</u> [3] for directives related to research activities at the University of Guelph.

Deadlines

If College-level review is required, your College will communicate its earlier internal deadlines.

Type Internal Deadline	Date Saturday, April 11, 2020 -	Notes
	5:00pm	Please submit all application documents, along with an OR-5 Form, to <u>research.services@uoguelph.c</u> <u>a.</u> [4]
External Deadline	Monday, April 20, 2020 -	
	2:00pm	Eligible Companies are required to submit their application through the COVID-19 Challenge

How to Apply

Eligible Companies are required to submit their application through the COVID-19 Challenge

website [1] prior to 2:00pm EDT

on April 20th, 2020.

Published on Research Alerts (https://www.uoguelph.ca/research/alerts)

website [1]

For Questions, please contact All incoming questions regarding this specific challenge should be addressed to <u>solutions@canada.ca</u> [5].

All inquiries must be submitted in writing no later than ten calendar days before the Challenge Notice closing date. Inquiries received after that time may not be answered.

You can also consult the <u>Frequently asked questions</u> [6] about the Innovative Solutions Canada Program.

Office of Research

Gregor Lawson, Industry Liaison Manager Research Innovation Office 519-824-4120 x54807 <u>lawsong@uoguelph.ca</u> [7] Alert Classifications**Category:** Funding Opportunities and Sponsor News

Disciplines:

Health and Life Sciences Information and Communications Technology Physical Sciences and Engineering

Source

URL:<u>https://www.uoguelph.ca/research/alerts/content/covid-19-challenge-%E2%80%94-point-care-and-home-diagnostic-kit-covid-19</u>

Links

- [1] https://www.ic.gc.ca/eic/site/101.nsf/eng/00100.html
- [2] http://www.ic.gc.ca/eic/site/101.nsf/eng/00002.html#eligibility
- [3] https://www.uoguelph.ca/research/article/2019-novel-coronavirus-information
- [4] http://research.services@uoguelph.ca./
- [5] mailto:solutions@canada.ca
- [6] http://www.ic.gc.ca/eic/site/101.nsf/eng/00004.html
- [7] mailto:lawsong@uoguelph.ca